CREATININE JAFFE 1+1 (2–8°C)

CATALOGUE NUMBER	KIT SIZE (ML)
MPRCRE3	1x100ml / 1x100ml / 1x5ml
MPRCRE4	2x100ml / 2x100ml / 1x5ml

Intended Use:
For *In Vitro* diagnostic use by trained professionals only.
This reagent is intended for the quantitative determination of creatinine in human serum, plasma and urine.

Clinical Significance:
Increased creatinine levels usually indicate renal function impairment but would not be considered a sensitive indicator of early renal disease. Plasma concentrations can be more sensitive to changes in glomerular function where a chronic renal disease state exists.
Urinary creatinine is only useful when performed as part of a creatinine clearance test. In these circumstances it is useful verification of the completeness of a 24 hour urine collection.

Test Principle:
Creatinine reacts with picric acid in an alkaline medium to form a deep yellow complex. The amount of complex formed is directly proportional to the level of creatinine in the sample and is measurable spectrophotometrically.

Reagent Composition

REAGENT	COMPONENT	CONCENTRATION
R1	Picric Acid	17.5 mmol/l
R2	Sodium Hydroxide	0.29 mol/l
Standard	Creatinine	177 µmol/l (2 mg/dl)

Precautions:
R1 (Picric Acid) and R2 (NaOH) and the working reagent are all corrosive. R35: Can cause severe burns. S26: In case of contact with eyes, rinse immediately with plenty of water and seek medical advice. S37/S39: Wear suitable gloves and eye/face protection. S45: In case of accident or if you feel unwell, seek medical advice immediately.

Reagent Preparation and Stability:
R1: Liquid, ready to use.
R2: Liquid, ready to use.
R1 and R2 are stable until the expiry date when stored unopened at 2 - 8°C.
Working Reagent: Mix equal volumes of R1 and R2. The Working Reagent is stable for 15 days at 2 - 8°C or up to 7 days at room temperature (15 - 25°C).
Signs of reagent deterioration include presence of particles, turbidity and a Blank absorbance at 492nm of ≥ 1.80.
Dispose of reagents carefully in line with local guidelines.
Sample Collection, Preparation and Stability:
Collect serum, plasma according to standard venepuncture technique and urine by established clinical procedure.
Creatinine is stable in serum and plasma for up to 24 hours at 2 - 8°C and up to 7 days in urine. Dilute urine 1/50 with distilled water prior to assay. Multiply the result by 50.

Assay Procedure:

WAVELENGTH	492 nm (490 – 510 nm)
TEMPERATURE	15 - 25/37°C
CUVETTE	1cm Path Length
BLANK	Reagent Blank

	Blank	Standard	Sample
Sample	-	-	100 µl
Standard	-	100 µl	-
Working Reagent	1000 µl	1000 µl	1000 µl
Mix and read absorbance A1 after 30 seconds and read absorbance A2 after a further 90 seconds. Calculate the absorbance (Δ Abs) of Sample/Standard against the Reagent Blank.			

Calculation:
Concentration (µmol/l / mg/dl) = $\frac{\Delta Abs\ Sample}{\Delta Abs\ Standard}$ x Concentration of Standard
Conversion factor: mg/dl x 88.4 = µmol/l.

Performance Characteristics:
Measuring range:
0.0 mg/dl to 35 mg/dl
Dilute samples with higher concentrations using Normal saline 1+1 and rerun the assay. Multiply the result by the dilution factor (for 1+1 dilution the dilution factor is 2).

Imprecision
Intra-Assay Precision:

Sample	Mean (mg/dl)	SD (mg/dl)	CV %
Pool 1	0.92	0.03	2.76%
Pool 2	3.43	0.07	1.90%

Inter-Assay Precision:

Sample	Mean (mg/dl)	SD (mg/dl)	CV %
Pool 1	0.96	0.04	3.97%
Pool 2	3.50	0.09	2.51%

Method Comparison:
Prestige Diagnostics Creatinine reagent (y) was compared with another commercially available reagent (x) and gave the following results:
y = 0.953 x + 0.075, r = 0.9958

Interferences:
Haemoglobin (1 g/l), Bilirubin (55 mg/dl) interfere in the assay. A list of drugs and other interfering substances with creatinine determination has been reported.

Reference Range:

Serum / Plasma		
Male	0.7 – 1.4 mg/dl	61.8 – 123.7 µmol/l
Female	0.6 – 1.1 mg/dl	53.0 – 97.2 µmol/l
Urine: 15 – 25 mg/Kg / 24hrs		
Male	10 – 20 mg/Kg/24 hrs	
Female	8 – 18 mg/Kg/24 hrs	

Each laboratory should establish its own mean reference range according to the population.

Automated systems:
Contact Prestige Diagnostics Technical Department for applications on a wide range of automated analysers.
For automated systems we recommend the use of a serum based calibrator.

Quality Control and Calibration Material:
Calibration Serum: **QCCCAL1 / QCCCAL2**
Human Assayed Control Normal: **QCCHAN1 / QCCHAN2**
Human Assayed Control Elevated: **QCCHAE1 / QCCHAE2**

Precautions:
Do not exchange reagents from different lots or use reagents from other commercially available kits. The components of the kit are precisely matched for optimal performance of the tests.
All specimens from human origin should be considered as potentially infectious. Adhere to strict Good Laboratory Practice regulations to ensure personal safety.
The result from this test should not be used as the sole criteria for the diagnosis of renal disorders, a confirmed diagnosis should only be made by a physician after all clinical and laboratory findings have been evaluated.

References:

1. Murray R.L. Creatinine. Kaplan A et al. Clin Chem. The C.V Mosby Co. St. Louis Toronto. Princeton 1984; 1261-1266 and 418.
2. Young DS. Effects of drugs on Clinical Lab Tests. 4th ed AACC 2001.
3. Young DS. Effects of disease on Clinical Lab Tests. 4th ed AACC 1999.
4. Burtis A et al. Tietz Textbook of Clinical Chemistry, 3rd ed AACC 1999.
5. Tietz NW et al. Clinical Guide to Laboratory Tests, 3rd ed AACC 1995.

REF	Catalogue number		Temperature limitation
	Consult instructions for use	LOT	Batch code
IVD	*In vitro* diagnostic medical device		Use by Date
	Manufacturer		

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